IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

UNITED STATES OF AMERICA, *ex. rel.* PATRICIA SIMON, and the STATES OF ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, INDIANA, LOUISIANA, MAINE, MARYLAND, MASSACHUSSETS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, *ex. rel.* PATRICIA SIMON, Plaintiffs-Relator, v. ABBOTT LABORATORIES, ABBOTT LABORATORIES INC., ABBOTT LABORATORIES INT'L CO., ABBOTT LABORATORIES PACIFIC, LTD., ABBOTT LABORATORIES SERVICES CORP., and ABBVIE, INC. Defendants.	Case No.: ____________ Not for Media Box or Pacer Jury Trial Demanded **FILED IN CAMERA AND UNDER SEAL PURSUANT TO THE FALSE CLAIMS ACT, *et al.***

TABLE OF CONTENTS

COMPLAINT

I. INTRODUCTION AND OVERVIEW

1. Between the years of 2005 and 2012, Abbott Laboratories concealed fatal and other serious side-effects associated with its flagship drug[1], Humira, in an effort to facilitate and escalate government reimbursement of the drug. By suppressing government and public knowledge of these effects, Abbott has successfully obtained several supplemental approvals from the United States Food and Drug Administration ("FDA") to market and sell Humira to an ever expanding array of patient populations, today totaling more than 12.5 million people in America alone, and encouraged healthcare providers and beneficiaries of state and federal health and drug programs to prescribe, purchase and submit claims for Humira even when they would not have done so had they been fully informed of such fatal and other serious side-effects. Humira generated over $7 billion in 2011, making it the highest grossing pharmaceutical product in the world. On May 7, 2012, as the United States Department of Justice announced that Abbott would settle fraud claims associated with another drug, Depakote, for $1.6 billion, Abbott announced that its stocks had risen 10 cents, largely on the strength of Humira. Motivated by greed Abbott ignored the well-being of the patients and hid adverse drug experiences associated with Humira from the FDA inducing reimbursement from government health plans.

2. In marketing and selling Humira, Abbott unlawfully concealed thousands of adverse drug experiences, including serious illnesses and fatalities, from the public, including Medicare, Tricare, Medicaid and other government beneficiaries, health care professionals and governmental agencies, including the Food and Drug Administration ("FDA"). Abbott's

[1] Throughout the Complaint, "drug" refers to both drugs and biological pharmaceutical products that must be approved, licensed and monitored by the FDA.

concealment of adverse drug experiences from the FDA ensured that physicians would not have knowledge of the side-effects of Humira and would continue to prescribe the drug; that researchers would not notice negative trends in the safety of Humira and continue to praise its reliability; that the FDA and government would continue to approve supplemental uses of Humira allowing for its expanding marketability; that Medicare, Tricare, Medicaid and other government beneficiaries would not hesitate to purchase Humira for an expanding area of indications; and, most importantly to Abbott, that Government Healthcare Programs would continue to reimburse Abbott for prescriptions of Humira.

3. On behalf of the United States of America and the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the District of Columbia and the City of Chicago, pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*. and similar state and municipal law provisions, Plaintiff and "Relator" PATRICIA SIMON files this *qui tam* Complaint, by her undersigned attorneys, ROBIN POTTER & ASSOCIATES, P.C., WANG LEONARD & CONDON, P.C., CROSS LAW FIRM, S.C., and KELLY & KING, P.C., against Defendants and alleges:

4. In violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*. and similar state and municipal law provisions, Defendant Abbott Laboratories collectively with its wholly-owned subsidiaries and recent spin-off company, AbbVie, Inc. ("Abbott" or "Defendant") knowingly presented or caused to be presented false or fraudulent claims to be submitted for payment or approval by federal and state agencies and/or programs by:

- Seeking and obtaining FDA approval to market and sell Humira as a treatment for a variety of chronic illnesses based on the certifications and representations that it was meeting its regulatory obligations to report adverse drug experiences;

- Intentionally concealing "adverse drug experiences," including severe health risks and fatalities, associated with Abbott's arthritis drug, Humira (generic name for adalimumab), despite certifications and representations to the government that it was reporting all adverse experiences.

5. Abbott is required by law, regulation, and FDA licenses to continue to monitor the dangers of these drugs, to timely and completely report serious and unexpected adverse drug experiences within 15 days and all other adverse drug experiences quarterly or annually to the FDA and to maintain a post-marketing pharmacovigilance program.

6. "Adverse drug experiences" encompass "any adverse event associated with the use of a drug in humans, whether or not considered drug related, including events occurring in the course of the use of a drug product in professional practices; from accidental or intentional drug overdose; drug abuse or withdrawal; and any failure of pharmacological action." 21 CFR § 310.80(b).

7. "Serious adverse drug experiences" include death, life-threatening adverse drug experiences that place the patient at immediate risk of death, inpatient hospitalization, persistent disability or incapacity, or congenital anomalies or birth defects.

8. "Unexpected adverse drug experiences" include any adverse drug experiences that are not in the current labeling for the pharmaceutical product or has never been previously observed. 21 CFR § 310.305(b).

9. Defendant Abbott Laboratories used three mechanisms, which when applied together, resulted in thousands of adverse drug experiences not being properly reported to the United States. First, Abbott routinely miscoded deaths and other serious consequences associated with Humira when used to treat non-FDA approved ailments ("off-label use") as

"expected," resulting in the events not being properly reported to the FDA. Second, Abbott maintained a decentralized post-marketing surveillance division designed to ensure that adverse drug experiences would not properly be reported to the FDA. Third, Abbott intentionally failed to adequately train employees and associates on how to identify adverse drug experiences, resulting in underreporting of these events.

10. While several government agencies from 2005 through present, including the FDA, have identified Abbott's failure to properly report adverse drug experiences associated with Humira, Defendant Abbott actively concealed the magnitude of its underreporting and repeatedly assured government agencies that it was taking corrective action. In fact, Defendant Abbott did not take corrective action and instead facilitated the continued concealment of adverse drug experiences associated with Humira.

11. A substantial percentage of Humira prescriptions are paid for by Medicare, Medicaid and other government-funded health insurance programs. However, these third-party payers will not reimburse drug manufacturers for drugs for which the FDA has proposed to withdraw approval, even prior to the actual withdrawal of approval. *See* 42 U.S.C. §1395y c(1)(C); 21 CFR § 355(e). The United States, by and through the FDA, was entitled to timely submissions of all adverse events associated with Humira by Abbott in order to make informed decisions on whether to continue to approve sales of the drug or reimburse Defendants for the drug.

12. The United States, by and through the FDA disseminates information regarding adverse events and related analysis, compilation and side-effect trends to healthcare providers and to the downstream Humira users, the beneficiaries of government health and drug programs. The purpose and effect of such dissemination of adverse event information is to deter usage of

and reimbursement for Humira, particularly when such side-effects might cause death or other patient harm or side effects which require additional government payments for related healthcare and drugs to address such side effects.

13. The concealment scheme alleged in this complaint was orchestrated and condoned at the highest levels of Abbott's management, some of whom benefitted financially from the exorbitant success of Humira. In carrying out these plans, which drained billions of health care dollars from public third party payers, Defendants knowingly placed at risk and caused injury to patients of all ages, from children suffering from Juvenile Idiopathic Arthritis, to elderly nursing home patients suffering from Rheumatoid Arthritis or Ankylosing Spondylitis. Millions of patients across the country, suffering from a variety of chronic illnesses, were given a dangerous drug without knowledge of the associated risk as a result of Abbott's concealment of serious adverse events, intended to maximize Abbott's profitability at the expense of the medical welfare of vulnerable patient populations.

14. Humira is within the class of biological pharmaceuticals known as a tumor necrosis factor ("TNF") inhibitor. The FDA first approved Humira to treat Rheumatoid Arthritis in 2002. Since that time the FDA has approved Humira to treat Plaque Psoriasis, Crohn's disease, Ankylosing Spondylitis, Psoriatic Arthritis, and Juvenile Idiopathic Arthritis. Abbott is currently seeking supplemental approval to market Humira as a treatment for six additional chronic illnesses: hidrandenitis suppurativa (a fulminating inflammatory skin disease); uveitis (an eye inflammation that can lead to permanent vision loss); axial and peripheral spondyloarthropathies, or SPA (two indications covering a group of wide-ranging inflammatory diseases); ulcerative colitis (an inflammatory bowel disease); and pediatric Crohn's disease.

15. Prior to Humira, two other TNF inhibitors had been on the market since 1998:

Enbrel (generic name for etanercept), marketed by Pfizer, and Remicade (generic name for infliximab), marketed in the United States by Janssen Biotech. Both are well-established drugs which have each been approved for same uses as Humira.

16. A recent study published by Thompson Reuters Healthcare comparing the "tnf-blocker cost per treated patient" of Humira, Enbrel and Remicade found that the cost to treat the average adult patient was $15,345 for Enbrel, $18,046 for Humira and $24,018 for Remicade. *See* "Costs per Treated Patient for Etanercept, Adalimumab, and Infliximab Across Adult Indications: A Claims Analysis," Bonafede, Machoan M.K.; Gandra, Shravanti R.; Watson, Crystal; Princic, Nicole; Fox, Kathleen M., *Advances in Therapy*, v. 29 i. 3, p. 234-248 (March 2012).

17. Abbott engaged in an extensive cover-up scheme in order to ensure continued government reimbursements of Humira for treatment of an expanding number of conditions. Total sales of Humira in the United States, from 2005 to 2011 exceeded $14 billion. Abbott's repeated promises and representations of compliance with reporting regulations to the United States, by and through the FDA, allowed for its supplemental applications for alternative uses of Humira to be approved, expanding the market for the drug. In 2011, Humira posted domestic sales of $3.427 billion, and international sales of $4.505 billion (up from $6.5 billion worldwide in 2010 and 5.4 billion in 2009), to some 585,000 patients, making it the highest grossing pharmaceutical product in the world.

18. As a consequence of Defendants' fraudulent concealment scheme, patients were placed at risk for numerous side effects, including fatal infections, fatal malignancies, fatal drug interactions, complete suppression of their immune system, dangerous infections, and malignancies. Patients taking Humira were also at risk of developing pneumonia, septic arthritis,

prosthetic and post-surgical infections, erysipelas, cellulitis, diverticulitis, or pyelonephritis. Patients taking Humira expect to take the drug for their entire lives, as the illnesses treated by Humira are chronic, exponentially increasing the risk that patients may suffer from these illnesses.

19. Government healthcare payers including Medicare, Medicaid, Tricare, the Veteran's Administration and other public health care plans, were harmed because they paid for Humira prescriptions unlawfully induced by Abbott's withholding necessary information regarding the serious health risks, including death, posed by the drug – information that would have influenced their decision to pay.

20. Moreover, these Government health payers also incurred the cost of treating Humira's significant side effects and the cost of delaying more appropriate and effective treatments.

21. Elderly patients, suffering from various arthritic illnesses, are often eligible for Government health care assistance from Medicare and or Medicaid and thus, Defendants knew or should have known that Abbott's unlawful concealment scheme would foreseeably result in the submission of false claims to Government health care payers. This includes payments on behalf of individuals receiving Veteran's Administration and Tricare benefits; moreover, virtually every American over the age of 65 is eligible for Medicare, which pays for prescriptions though Medicare Part D. Elderly patients who exhaust their own personal resources become eligible for expansive prescription coverage through Medicaid programs. Thus, Defendants knew that their illegal concealment scheme was directed at individuals whose health care providers would submit false claims to be paid by the Government. A fraud on the beneficiaries and their healthcare providers constitutes a fraud on the Government payer.

22. Abbott's profits soared and its top officials received astronomical compensation packages including salary, stocks, and options, at least in part, at the Government's expense. According to Abbott's 2012 Proxy Statement, senior executives at Abbott are paid performance bonuses based on annual sales and participate in a bonus pool made up of a percentage of Abbott's net earnings. Therefore, boosting sales through concealment of adverse events directly translated (and still translates) to higher bonuses for Abbott's top level executives.

23. Relator Patricia Simon has firsthand knowledge of Abbott's worldwide scheme to conceal adverse experiences associated with Humira. Relator was employed in Abbott's Global Pharmacovigilance division. Her responsibilities included attempting to ensure that Abbott remained in compliance with its post-marketing reporting obligations, both in the United States and internationally, and reporting these events to the FDA in accordance with federal regulations. Relator witnessed, and brought to the attention of her supervisors, several practices that had the purpose, effect or design, to ensure that adverse experiences were not reported in a timely manner or at all.

24. Abbott also went one step beyond withholding reports of adverse drug experiences from the United States and intentionally suppressed knowledge of the post-marketing surveillance structure designed to conceal such events, by ordering employees not to report the system to government authorities. In November 2010, Relator was ordered by Abbott to suppress knowledge of its fraudulent post-marketing surveillance structure during an FDA audit.

25. Through its illegal concealment of adverse events, Abbot significantly increased the market for Humira, which resulted in markedly increased revenue from that drug at the expense of federal, state and local governments. Humira has been heavily promoted in

television, print, and internet direct to consumer advertising. As part of its plan to achieve this level of sales, Abbott has under-reported and delayed reporting of serious adverse events related to Humira use, some of which required expedited 15-day reporting to the FDA.

26. The government healthcare plans, by and through the FDA, are entitled to timely and complete submissions of all adverse drug experiences associated with Humira in order to make informed decisions on whether to reimburse for the drug. Abbott's failure and refusal to timely submit all adverse drug experiences associated with Humira, deprived federal and state programs, including Medicare, Medicaid, Tricare, Veteran's Administration and other public health care payers, of material information that would have influenced their decision to reimburse the drug.

27. The government healthcare plan beneficiaries and their healthcare providers, by and through the FDA, are entitled to timely and complete submissions of all adverse drug experiences associated with Humira. In an October 4, 2012 paper, the FDA's Office of Surveillance and Epidemiology (OSO) stressed that "every report matters" precisely because just one single report is material to the end-user's decision to take Humira.

28. Abbott's business model to withhold or delay adverse event reporting, as more fully described herein, is intentionally designed to deny the government beneficiaries and their healthcare providers information material to their decision of whether or not to prescribe and use Humira.

29. Ms. Simon was ultimately demoted in 2011 for repeatedly recommending or attempting proper reporting of adverse drug experiences related to Humira.

II. JURISDICTION AND VENUE

30. Relator brings this action on behalf of herself and on behalf of the United States

for violation of the False Claims Act, 31 U.S.C. §§3729-3733, the States, the District of Columbia and the City of Chicago for violations for their False Claims Act statutes. This Court has federal subject matter jurisdiction pursuant to on 28 U.S.C. §1331 and 31 U.S.C. §3732, and supplemental jurisdiction over the counts relating to the States, the District of Columbia and the City of Chicago False Claims Act statutes pursuant to 28 U.S.C. §1367.

31. This Court has personal jurisdiction over the defendant pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in and transacts substantial business in this district.

32. Venue is proper in the Eastern District of Wisconsin pursuant to 31 U.S.C. 3732(a) and 28 U.S.C. 1391(b) because the defendant can be found in and transacts business in this district.

33. Relator has direct and independent knowledge, within the meaning of 31 U.S.C. §3730(e)(4)(B) of the information on which the allegations set forth in this Complaint are based.

34. Relator is the original source of the allegations as defined in 31 U.S.C. §3730(e)(4)(B). Relator has knowledge of the false statements, records, and claims that Defendant knowingly submitted to the Government as alleged herein.

35. Previous to the filing of this Complaint, Relator voluntarily disclosed the allegations herein to the government.

36. To the extent, if any, that this case is deemed to be a related action and that facts set forth herein are deemed to be the same as facts underlying an existing *qui tam* False Claims Act action pending at the time of filing of this action, as provided in 31 U.S.C. §3730(e), and to the extent said cases are not consolidated, said same claims are hereby expressly excluded to the limited extent necessary to exclude such preemption.

37. Furthermore, to the extent that the Court finds that the allegations or transactions

set forth herein are based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party, if any such proceedings exist, then the allegations of transactions referred to herein that the Court deems are based on upon allegations or transactions which are the subject of any such civil suit or administrative civil money penalty proceeding are expressly excluded for the specific time periods, specific companies, and specific allegations or transactions as necessary, and in the event said suits are not consolidated with the instant suit.

38. There has been no statutorily relevant public disclosure of the allegations or transactions in this Complaint. Relator is an original source under the Act even if such public disclosure were found to exist because she has direct and independent knowledge of the wrongdoing alleged in this Complaint and because she voluntarily provided this information relating to such misconduct to the United States prior to initiating this *qui tam* suit.

III. PARTIES

39. Relator Patricia Simon, RN, is a resident of Mount Prospect, Illinois. Relator is a trained, licensed Registered Nurse ("RN") with a Masters of Science in Health Services Administration. She worked as a staff Nurse at Evanston Hospital from 1987 to 1996. From 1996 through 2000 she was employed by Kendle, a contract research organization, as a Safety Specialist to identify and document reports of adverse drug experiences.

She was employed by Abbott starting in June 2000. She worked in the post-marketing surveillance division of Abbott for her entire tenure. She was trained on how to identify adverse drug experiences and how to report them to the FDA. She has also independently studied the FDA regulations governing pharmaceutical manufacturer reporting obligations and is intimately familiar with them. For the years 2007 through 2012, Relator was Assistant Director of Post-

marketing Safety within the Global Pharmacovigilance division of Abbott. Her responsibilities included ensuring that Abbott remained in compliance with its post marketing reporting obligations. In this role Relator participated in several audits, assisting the auditors in assessing the effectiveness of Abbott's post-marketing surveillance division.

She also conducted several internal investigations to determine whether Abbott was meeting its regulatory requirements. After conducting an informal audit in December 2010, Relator determined that Abbott was not meeting its requirements to adequately report adverse drug experiences related to Humira. Relator reported her findings to her supervisors in January 2011. Abbott took no corrective action to ensure that adverse drug experiences associated with Humira would be reported to the FDA as required. Relator, however, was demoted from her management position in January 2012. Relator resigned from her position at Abbott on April 5, 2012.

40. Abbott is an Illinois corporation having its corporate headquarters and principal place of business in Abbott Park, Illinois. Abbott engages in the global business of development, manufacturing, marketing, and sale of prescription drugs and other products for the prevention, diagnosis, and treatment of diseases. According to its 2011 10-K annual report filed with the United States Security and Exchange Commission, Abbott generated a net revenue of $38.8 billion in the fiscal year ending December 31, 2011, with Humira accounting for $7.9 billion of the 2011 sales

41. Abbott Laboratories, Inc. is a Delaware corporation registered in Illinois as a foreign corporation and is a wholly-owned subsidiary of Abbott.

42. Abbott Pharmaceuticals North America, Inc. is a wholly owned U.S. subsidiary organized under the laws of Delaware and has its principal place of business in Abbott Park,

Illinois.

43. TAP Pharmaceutical Products, Inc. ("TAP"), was another TPC subsidiary. In 2001, TAP pled guilty to various charges arising out of their "fraudulent drug pricing and marketing conduct" with regard to Lupron, an Abbott drug used to treat prostate cancer. To avoid prosecution, TAP pled guilty to conspiracy to violate the Prescription Drug Marketing Act and paid a $290,000,000 criminal fine (which at the time was the largest criminal fine ever in a health care fraud prosecution), agreed to settle its federal civil FCA liabilities and to pay the U.S. Government $559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs for its fraudulent drug pricing schemes and sales and marketing misconduct. TAP also agreed to comply with the terms of a sweeping Corporate Integrity Agreement, which, among other things, required it to deal honestly with the United States and the Medicare and Medicaid programs. Abbott and Takeda ended the TAP venture in 2008.

44. AbbVie, Inc. is Abbott Labs' research-based pharmaceutical business, including its primary drug, Humira, which spun off from Abbott to create its own publically traded company on January 1, 2013. Its principal offices are located at 1 North Waukegan Road, North Chicago, Illinois, 60064 and its president and chief executive officer is Richard A. Gonzalez. AbbVie, Inc. receives payment for its sales of Humira.

IV. ABBOTT'S PRESCRIPTION DRUG HUMIRA

A. Humira's FDA-Approved Uses and Restrictions, and Revenue

45. Adalimumab injectable pre-filled syringes marketed by Abbott under the brand name "Humira," were first approved by the FDA in 2002 for treating Rheumatoid Arthritis. The drug was approved to treat adult patients with "moderately to severely active rheumatoid

arthritis." The approval letter stated "[i]t is required that adverse experience reports be submitted in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80)." *Id.* Rheumatoid Arthritis affects roughly 2 million Americans.

46. Humira generated $246 million in sales in the United States, and an additional $34 million internationally, in 2003.

47. In 2003, Abbott's supplemental application to market an altered the pre-filled syringe mechanism was approved by the FDA.

48. Humira generated $852 million in sales worldwide in 2004.

49. In October 2005, Abbott's supplemental request to the FDA to market Humira as a treatment for Psoriatic Arthritis was approved. Psoriatic Arthritis affects roughly 1 million Americans.

50. Humira generated $1.4 billion in sales worldwide in 2005.

51. In 2006, Abbott's supplemental request to the FDA to market Humira as a treatment for Ankylosing Spondylitis was approved. Ankylosing Spondylitis affects roughly 1 million Americans.

52. In 2006, Abbott's supplemental request to FDA to market a new medical device for administering Adalimumab, the Humira Pen ("Humira Pen"), was approved. Abbott began sales of the Humira Pen in 2006.

53. Humira generated $1.2 billion in sales in the United States, and an additional $868 million internationally, in 2006.

54. In February 2007, Abbott's supplemental request to the FDA to market Humira as a treatment for Crohn's Disease was approved. Crohn's Disease affects roughly 500,000 Americans.

55. Humira generated $1.6 billion in sales in the United States, and an additional $1.4 billion internationally, in 2007.

56. In January 2008, Abbott's supplemental request to the FDA to market Humira as a treatment for moderate to severe Plaque Psoriasis was approved. *See* FDA Letter dated January 18, 2008. Plaque Psoriasis affects roughly 7.5 million Americans.

57. Soon thereafter, Abbott's supplemental request to the FDA to market Humira as a treatment for Juvenile Idiopathic Arthritis was approved. More than 290,000 children suffer from Juvenile Idiopathic Arthritis and may be diagnosed as early as 24 months old.

58. Humira generated $2.2 billion in sales in the United States, and an additional $2.3 billion internationally, in 2008.

59. Since 2008 Humira has been marketed to patient pool of nearly 12.5 million Americans, all suffering from lifelong illnesses which have no cure, merely amlerioative treatments. Humira generated another $2.52 billion in sales in the United States, and an additional $2.97 billion internationally, in 2009. Humira generated $2.872 billion in sales in the United States, and an additional $3.677 billion internationally, in 2010. Finally, Humira generated $3.427 billion in sales in the United States, and an additional $4.505 billion internationally, in 2011. In total, since Abbott's most recent supplemental treatment approval in 2008, Humira has generated $8.819 billion in the United States and $19.971 billion overall in world-wide services.

B. Safety Issues: Humira's Black Box Warnings

60. The FDA does not perform studies or test to independently determine the safety and efficacy of pharmaceutical products prior to approving their sale to the public or after the drug has been approved. FDA regulations, however, mandate that pharmaceutical manufacturers

keep a detailed account of the effects of its products. To the extent a manufacturer learns about reported cases of side effects (i.e. adverse effects), severe or not, that are associated with any use of the product, the FDA requires manufacturers to report the effect to the FDA and the FDA may issue a warning letter to physicians and other health care providers. By not reporting adverse effects manufacturers cripple the ability of the FDA to monitor the safety and efficacy or to adequately warn physicians about the risk associated with the pharmaceutical.

61. In August 2006, the FDA issued a "black box warning" (the most stringent warning it can issue short of recall) regarding Humira's safety. The FDA required Abbott to change its product labeling and to send letters to health care providers that warned of a life-threatening side effect. The black box warning states in part:

> Tuberculosis (frequently disseminated or extra pulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections, have been observed in patients receiving Humira. Some of these infections have been fatal (see warnings). Antitubercolosis treatment of patients with latent tuberculosis infection reduces the risk of reactivation in patients receiving treatment with Humira. However, active tuberculosis has developed in patients receiving Humira whose screening for latent tuberculosis infection was negative.

62. In November of 2009, the FDA issues a second black warning regarding the safety of Humira. The FDA required Abbott to change its product label once again and notify all health care providers that Humira presented more life-threatening illnesses. The black box warning states in pertinent part:

> SERIOUS INFECTIONS
> • Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
> • HUMIRA should be discontinued if a patient develops a serious infection or sepsis during treatment.

• Perform test for latent TB; if positive, start treatment for TB prior to starting HUMIRA.
• Monitor all patients for active TB during treatment, even if initial latent TB test is negative. (5.1)

MALIGNANCY
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which HUMIRA is a member.

63. The FDA's black box warnings on the use of Humira remain in effect today.

C. Humira's Other Warnings, Precautions and Serious Side Effects

64. In addition to the black box warnings Humira's package insert lists a wide array of illnesses and conditions that patients may contract as a result of Humira. In particular, patients taking Humira could develop a lupus-like syndrome, Elevated Liver Enzymes, Immunogenicity, Upper respiratory infection, Sinusitis, Flu syndrome, Nausea, Abdominal Pain, Abnormal Laboratory Tests, or Hypercholesterolemia.

65. Humira also poses risks to children who may be taking the drug to treat Juvenile Idiopathic Arthritis. Children treated with Humira experience adverse reactions "similar in frequency and type to those seen in adult patients" but include additional side effects, many fatal. Those side effects include: Neutropenia, Stretptococcal Pharyngitis, Increased Aminotransferases, Herpes Zoster, Myositis, Metrorrhagia, Appendicitis, and Serious Infections such as Herpes Simplex, Pneumonia, Urinary Tract Infection, Pharyngitis and Herpes Zoster. Children treated with Humira are more likely to have localized hypersensitivity reactions and allergic rash, moderate elevations of liver aminotransferases, mild to moderate elevations of creatine phosphokinase ("CPK").

66. Post-marketing safety monitoring for Humira (Serious Adverse Events or Adverse Events reported by Medical Personnel, Hospitals, Patients, and through other means) disclosed additional side effects including diverticulitis, large bowel perforations, appendiceal perforations, pancreatitis, interstitial lung disease, pulmonary fibrosis, Stevens Johnson syndrome, cutaneous vasculitis, erythema multiforme, new or worsening psoriasis (all sub-types) and systemic vasculitis.

67. Finally, Humira interacts with all drugs in its class of drugs as well as Methotrexate (which is thought to reduce Humira clearance), Anakinra, Abatacept, Rituximab, and any live vaccine. Specifically, no live vaccine of any type is to be co-administered with Humira therapy.

V. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANT'S FALSE CLAIMS ACT VIOLATIONS

A. THE FALSE CLAIMS ACT

68. The Federal False Claims Act provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false record or statement material to a false or fraudulent claim is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal government. 31 U.S.C. § 3729(a)(1)(A)&(B). Twenty-four states, the District of Columbia and the City of Chicago have enacted False Claims Act statutes that apply to Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds.

69. A "statement is material if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed.'" Neder v. United States, 527 U.S. 1, 16, 119 S. Ct. 1827, 144 L. Ed. 2d 35 (1999) (quoting from *Kungys v. United States*, 485 U.S. 759, 770, 108 S. Ct. 1537, 99 L. Ed. 2d 839 (1988)). A statement is capable of influencing a decision "even if those who make the decisions are negligent and fail to appreciate the statement's significance." U.S. v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008). Whether an omission or misrepresentation could have influenced the decision maker's decision is "an objective standard." Id.

70. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time). Based on these provisions, *qui tam* plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

71. Recently, the Patient Protection and Affordable Care Act ("PPACA"), public Law No. 111-148, Sec. 6402(g), amended the "Social Security Act," 42 U.S.C. §1320a-7b(b), to broaden the scope of violations that can be enforced through the False Claims Act. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of provisions of the Social Security Act, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

B. FEDERAL HEALTH CARE PROGRAMS

72. The federal, state and local governments, through their Medicare, Medicaid,

Tricare, Veteran's Administration and other Government health care payers, are among the principal purchasers of Abbott's pharmaceutical products.

73. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. Entitlement to Medicare is based on age, disability or affliction with certain diseases. See 42 U.S.C. §1395 to 1395 ccc. Outpatient prescription drugs are covered under Parts A-D of the Medicare Program.

74. In 1965, the federal government also enacted the Medicaid program. It is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP"). Outpatient prescription drugs are covered under the Medicaid Program as long as they meet the definition of a "Covered Outpatient Drug."

75. Medicaid has broad coverage for prescription drugs, including self-administered drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

76. Tricare is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military

operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and career military retirees and their dependents. The program operates through various military-operate hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. Tricare is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

77. Whereas Tricare treats active duty military and their dependents, the Veterans Administration ("VA") provides health care and other benefits to veterans of the military through its nationwide network of hospitals and clinics.

78. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

79. Pharmaceutical drugs are also used on an inpatient basis, purchased by nursing homes, hospitals, and other facilities for inpatients. Generally, in such settings, the provider does not separately bill the Government Healthcare Programs for the drug; rather, the provider is reimbursed based upon a composite rate, a daily rate, the actual cost, or a combination. Even so, federally funded Government Healthcare Programs such as Medicare Part A, Medicaid inpatient, and TRICARE inpatient benefit are damaged when they pay for pharmaceuticals that have been paid for in violation of the FCA.

80. Under the Medicare Act, 42 U.S.C. §1395y(a)(1)(A), there is an express

fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE and other federally funded programs restrict coverage under the same principle.

81. Hospitals and other inpatient facilities participating in the Medicare, Medicaid and other federally funded Government Healthcare programs are required to file annual cost reports with the appropriate agencies. When a provider submits a Medicaid cost report which includes requests for payment for pharmaceuticals that were not reasonable and necessary, the claims for those expenses are legally false.

C. FDCA AND FDA REGULATIONS

82. The United States Food and Drug Administration ("FDA") regulates drugs and drugs based on consistent monitoring of the safety and efficacy of the product. Before marketing and selling a prescription, and consistently while the product is on the market, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. §331(d); 21 U.S.C. §§355(a). The FDA, pursuant to its statutory mandate, regulates and monitors the approval, manufacture, processing, packing, labeling and shipment in interstate commerce of pharmaceuticals.

83. To ensure that consumers are receiving safe and effective drugs, the United States Congress, through various amendments, enacted the Food, Drug, and Cosmetic Act ("FDCA"), which requires that a drug manufacturer be licensed to commercially market the drug, 42 U.S.C. Sec. 262(a)(1), and that the drug manufacturer be approved through a New Drug or Biologics Application ("NDA" or "BLA") prior to commercially marketing the drug. 21 U.S.C. § 355(a).

84. To obtain approval, the manufacturer must undertake to conduct, and submit the results of, investigations in animals and humans that demonstrate that the drug is safe and effective for its intended uses and other information pertinent to an evaluation of the safety and effectiveness of the drug. 21 U.S.C. §355; see also 21 C.F.R. §. 314.50 (detailing disclosures made in NDA) and 21 C.F.R. § 600.2 (detailing the same disclosures for BLA). The FDA evaluates the safety and effectiveness of the drug and approves the directions for use and cautionary information in the labeling for the drug on the basis of the information supplied to it by the manufacturer. The FDA does not conduct its own tests of the drug. It relies on the manufacturer to inform it of adverse reaction reports. Thus, the FDA's ability to evaluate a drug's safety and efficacy and to protect the public adequately depends expressly on the manufacturer's reports of timely, accurate and complete data to FDA.

85. Manufacturers apply for a license to sell pharmaceutical products either through the NDA or BLA. The initial application for either New Drug or Biologics license requires the manufacturer to promise, among other things, to monitor adverse events. The application requires manufacturers to make the following certification (*emphasis* added):

> **CERTIFICATION**
> I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:
>
> 1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
> 2. Biological establishment standards in 21 CFR Part 600.
> 3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
> 4. In the case of a prescription drug or biological product,

prescription drug advertising regulations in 21 CFR Part 202.

5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. *Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.*
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision. The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

86. After the drug has been approved for commercial marketing, the FDCA and applicable regulations require the manufacturer to establish and maintain records and reports that will enable the FDA to continue to evaluate the safety and effectiveness of the drug and, when appropriate, withdraw the Application or change the labeling. 21 U.S.C. Sec. 355(k); 21 C.F.R. §§314.80, 314.81, 600.80, 600.81and 601.27.

87. To obtain approval from the FDA for supplemental uses of the product, those not initially approved by the FDA, the manufacturer must submit an additional application containing all of the same information required in the initial FDCA section 505(b)(1) application, save for bioavailability or bioequivalence studies, using a FDCA section 505(b)(2) application. That supplemental form application contains full reports of investigations of safety and effectiveness but some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference such a post-marketing pharmacovigilance safety monitoring. Thus, for each supplemental indication Abbott again confirmed it had, was, and would fully comply with its post-marketing safety monitoring of "adverse drug experiences."

88. An "adverse drug experience," in the context of biological products like Humira, is defined as "any adverse event associated with the use of a biological product [or drug] in humans, whether or in not considered product-related [or drug related]." 21 C.F.R. Sec. 600.80(a) (defining "adverse drug experience" for biologics); *see also* 21 C.F.R. §314.80(a) (defining "adverse drug experience for drugs").

89. Specifically in regards to biologics, like Humira, adverse experiences include "adverse event[s] occurring in the course of the use of a biological product in professional practice; an adverse event occurring from overdose of the product whether accidental or intentional; an adverse event occurring from abuse of the product; an adverse event occurring from withdrawal of the product; and any failure of expected pharmacological action." 21 CFR § 600.80(a). The regulation outlines three types of adverse experiences:

- **Life-threatening adverse experience.** Any adverse experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred, i.e., it does not include an adverse experience that, had it occurred in a more severe form, might have caused death.

- **Serious adverse experience.** Any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

- **Unexpected adverse experience:** Any adverse experience that is not listed in the current labeling for the biological product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the

labeling only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

90. Nearly identical definitions exist for "adverse drug experiences," as defined by regulation. 21 CFR § 314.80(a).

91. The FDA has promulgated 21 C.F.R. §314.80 and 314.81 and 21 C.F.R. §600.80 and 600.81 which requires expedited and accurate reports of post-marketing serious and unexpected adverse drug experience and adverse drug experiences by drug and biologics manufacturers. The manufacturer must report information pertinent to the safety and effectiveness of the drug or biologic from any source, including unpublished reports of clinical experience not previously submitted to the FDA. The regulations require the manufacturer to report within 15 days all serious and unexpected adverse experiences or injuries associated with the drug or biologics in a 15-day "Alert Report." 21 C.F.R. §§ 314.80(c)(1)(i); 600.80(c)(1)(i). The manufacturer must report all other adverse reactions to the FDA in quarterly periodic reports during the first three years following approval, and then thereafter at annual intervals in a Periodic Safety Update Report ("PSUR"). 21 C.F.R. §§ 314.80(c)(2), 600.80(c)(2).

92. Annual Reports are submitted through FDA Form 2252, which notes that "[t]his report is required by law (21 USC 355; 21 CFR 314.81). *Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.*" (emphasis added).

93. FDA regulations for drug manufacturers having obtained a New Drug or Biologics License provide that the manufacturers "shall promptly review all adverse experience information pertaining to its product obtained or otherwise received by the licensed manufacturer from any source, foreign or domestic, including information derived from

commercial marketing experience, post-marketing clinical investigation, post-marketing epidemiological surveillance studies, reports in the scientific literature and unpublished scientific papers." 21 C.F.R. § 600.80(b); *see also* 21 CFR § 314.80(b) (for new drugs).

94. The regulations further provide that "any person subject to the reporting requirements . . . shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to FDA." 21 C.F.R. Sec. 600.80(b); *see also* 21 C.F.R. §314.80(b).

95. Strong policy reasons exist for strict regulation of adverse event reporting. Failure to report adverse events to the United States, by and through the FDA, and the public bypasses the FDA's strict monitoring process, and limits the ability government third party payors, physicians and researchers, to determine the true efficacy and safety of the drug when administered to the general public, as opposed to test groups used prior to FDA approval, and makes it impossible to recognize trends in the side effects of the drug on a population. By concealing adverse events a manufacturer can ensure continued renewal of its FDA license, approval of supplemental uses, and government reimbursements, despite the hidden dangers of exposing the public to the pharmaceutical.

96. A manufacturer's failure to comply with the FDCA reporting obligation constitutes a "prohibited act" under the FDCA subjecting the manufacturer to various civil and criminal penalties, including but not limited to withdrawal of the approval of the NDA and/or revocation of a Biologics License (i.e., prohibiting the continued marketing of the drug), injunctive orders, monetary fines and up to one year imprisonment. *See* 21 U.S.C § 331(e); 21 U.S.C § 332(a); 21 U.S.C § 333(a)(1); 21 U.S.C. § 355(e); and 21 C.F.R. §§ 600.80(j), 314.80(j).

97. The FDA does not test or study the safety and efficacy of pharmaceuticals, either prior to market approval or post-market approval; however the FDA does conduct inspections of manufacturer facilities and audits of manufacturer records to ensure compliance with the FDA regulations.

98. After an FDA inspection the FDA may issue a Form 483 outlining "Inspectional Observations" regarding the manufacturer's compliance with FDA regulations. Once a Form 483 has been issued the manufacturer has 15 days to respond to the FDA, addressing each observation, indicating agreement with the observation and providing a timeline for correction or a request for clarification. Based on the manufacturer's response the FDA makes a determination of whether to take further action, including the issuance of a Warning Letter, withdrawing approval of the product or shutting down a plant.

99. The FDA may withdraw its approval of a drug or biologic if it finds that "the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation." 21 CFR § 355(e).

100. The Social Security Act expressly excludes payment by the Federal Government for drugs which the FDA has "issued a notice of an opportunity or hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling"

101. Abbott's unlawful concealment of adverse drug experiences associated with Humira, and subsequent misrepresentations of strict adherence to its reporting obligations,

repeatedly violated the FDCA, which in turn resulted in violations of the False Claims Act, because Abbott's unlawful material misrepresentations induced physicians to prescribe Humira and government-funded health insurance programs to reimburse for the drug, when timely submissions of adverse event reports were capable of influencing the governments' decisions to reimburse. *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 51-53 (D. Mass. 2001).

VI. SPECIFIC ALLEGATIONS OF DEFENDANT'S FALSE CLAIMS

A. ILLEGAL CONCEALMENT OF ADVERSE EXPERIENCES ASSOCIATED WITH HUMIRA

102. Abbott concealed adverse experiences associated with Humira, and suppressed knowledge of its decentralized reporting mechanism, in direct violation of federal regulations, in order to obtain approval for supplemental uses for the drug, vastly expanding its marketability, and to avoid recall and/or termination of federal reimbursement for Humira prescriptions in the face of increased scrutiny over the safety and efficacy of the drug.

1. Abbott ignored a 2005 warning from the FDA that it had not developed any procedures for the evaluation and reporting of adverse events to the FDA

103. In 2005, Abbott was issued an FDA Form 483 detailing 20-pages worth of observations made during an FDA inspection of Abbott's facilities, including an inspection of Abbott's post-marketing safety structure.

104. The Form 483 identified several deficiencies in Abbott's reporting of adverse drug experiences. In particular the FDA observed the following:

- "written procedures have not been developed for the surveillance, evaluation and reporting to the FDA of post marketing adverse events."
- "Abbott Laboratories procedures for surveillance and receipt of adverse events (ADE's) from patient assistant programs do not describe activities to be performed by all Abbott Laboratories employees and contractors to identify potential ADE's

and collect the data required for reporting. As a result when deaths have been reported to Abbott's patient assistance program no efforts are made at the time of the initial consumer contact to obtain the data elements require for reporting. Furthermore follow-up is not initiated on an expedited basis."

- "Abbott Laboratories procedures for evaluation of adverse event data were not sufficient to identify the . . . post marketing surveillance adverse drug event cases of deaths concomitant with Humira 40 mg/.8mL Pre-filled Syringe therapy as serious and unexpected. The initially received information for these events documented only death and was not qualified as to the cause of death" As a result, Abbott classified these events as requiring periodic reporting and did not report these events on an expedited basis."

- "Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of information." In particular, the FDA found that 147 serious adverse drug experiences in a two year span were not timely reported to the FDA.

105. Abbott responded to the Form 483 observations by letter on April 27, 2005. In it Abbott categorically denied the observations and asserted that its procedures meet FDA reporting obligations.

106. Abbott failed to take corrective action in repose to the 2005 FDA observations.

2. Abbott has failed to report hundreds of deaths and other serious consequences associated with the off-label use of Humira, concealing the risks associated with the drug.

107. Abbott had, from at least 2005 through 2010, created and maintained procedures designed to result in reduced reporting of adverse drug experiences associated with Humira as serious and unexpected events, thereby evading detection of the safety and efficacy of the product.

108. Relator is aware that from 2005 through 2010 Abbott ordered all individuals tasked with receiving and reporting adverse drug experiences to designate all adverse events received by Abbott in which a death or serious adverse event occurred associated with Humira as an "expected" event if it was described on the label, and thus not subject to expedited

reporting to the FDA.

109. Abbott justified this policy by maintaining that because the package insert included with all prescriptions of Humira listed "death" and other serious adverse events as a potential side effect, they were expected events and should not be listed as "unexpected."

110. Abbott applied this convention to all adverse events reported to it, including those in which Humira was being used for an "off-label" use, a use for which the FDA has not approved Humira.

111. All adverse events arising from off-label use of Humira are, by definition, unexpected, as the product is only intended to be used as a treatment for those ailments for which the drug has been approved by the FDA.

112. Even still, Abbott did not report deaths and other serious adverse events associated with Humira for off-label use in an expedited fashion to the FDA. Instead, Abbott either failed to report the event or buried these events in its yearly report of all expected and non-serious events to the FDA.

113. Relator, in investigating Abbott's failure to properly report adverse drug experiences associated with Humira to the FDA, identified as a an example of Abbott's failed reporting dozens of cases of serious and unexpected adverse drug experiences associated with the use of Humira for treatment of off-label ailments, which were not properly reported to the FDA.

114. In particular, Relator identified four cases in which a serious and unexpected adverse drug experience associated with Humira while being used to treat Hidradenitis, a use not approved by the FDA, was received by Abbott but not properly reported to the FDA:

- Case 08P-028-0472026- Case from Canada in which Humira was associated with the onset of breast cancer while being used to treat Hidradenitis. The adverse

drug experience is both serious and, because it is off-label, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report, but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 08P-144-0455640 - Case from Spain in which Humira was associated with the onset of facial cellulitis while being used to treat Hidradenitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 11P-144-0712892- Case from the United States in which Humira was associated with the onset of ankle arthrodesis and rash psoriaform while being used to treat Hidradenitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 12P-036-0893864 – Case from the United States in which Humira was associated with the onset of dermic lesions while being used to treat Hidradenitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

115. Based on Relator's observations these cases are merely a small example of hundreds of serious and unexpected adverse drug experiences associated with Humira for treatment of Hidradenitis Abbott failed to properly report to the FDA from at least 2005 through 2010.

116. Relator also identified five cases in which a serious and unexpected adverse drug experience associated with Humira while being used to treat Ulcerative Colitis, a use not approved by the FDA, was received by Abbott but not properly reported to the FDA:

- Case 09P-163-0592111-00- Case from United States in which Humira was associated with burning at the injection site while being used to treat Ulcerative

Colitis. The adverse drug experience is both serious and, because it is off-label, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report, but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 09P-163-0607709-00- Case from United States in which Humira was associated with the onset of a knot under the skin at the injection site while being used to treat Ulcerative Colitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 09P-163-0591419-00- Case from the United States in which Humira was associated with burning and the onset of rashes at the injection site while being used to treat Ulcerative Colitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 09P-163-0604907-00– Case from the United States in which Humira was associated with the onset of a heart rate of 200, swollen mitral valve in the heart and atrial fibrillation, while being used to treat Ulcerative Colitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

- Case 09P-163-0599304-00– Case from the United States in which Humira was associated with persistent pain at the injection site while being used to treat Ulcerative Colitis. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

117. Based on Relator's observations these cases are merely a small example of hundreds of serious and unexpected adverse drug experiences associated with Humira for treatment of Ulcerative Colitis Abbott failed to properly report to the FDA from at least 2005 through 2010.

118. Relator also identified cases in which an adverse drug experience associated with Humira while being used to treat Uveitis, a use not approved by the FDA, was received by Abbott but not properly reported to the FDA. For example, Relator identified case 09P-163-0603949-00, a case from the United States in which Humira was associated with the onset of rectal cancer. The adverse drug experience is both serious and, because of its off-label use, unexpected. The adverse drug experience should have been reported to the FDA as an "alert 15 day" report but was instead never identified as a serious and unexpected event, making it impossible for the FDA to discover during a review of its records or an audit.

119. Based on Relator's observations these cases are merely a small example of hundreds of serious and unexpected adverse drug experiences associated with Humira for treatment of Uveitis Abbott failed to properly report to the FDA from at least 2005 through 2010.

120. Abbott is currently seeking FDA approval of Humira as a treatment for Hidradenitis, Ulcerative Colitis and Uveitis.

121. In 2010, the FDA issued Abbott a Form 483 Notice after conducting an inspection of Abbott's Global Pharmacovigilance division, charged with reporting to the FDA all adverse drug experiences reported to Abbott. The Form 483 Notice identified 62 cases of death reported to Abbott from January 1, 2010, through November 17, 2010, which were not properly reported to the FDA.

122. Based on Relator's knowledge each of the 62 cases of death identified in the 2010 FDA Form 483 Notice is associated with Humira.

123. Based on Relator's observations each of the 62 cases of death identified in the 2010 FDA Form 483 Notice was not reported to the FDA as a result of Abbott's unlawful order

to designate all cases of death and other serious adverse events, which are identified on the Humira package insert, as "expected" events despite occurring while the drug was being used for an off-label purpose.

124. Abbott responded to the FDA Form 483 Notice by letter on January 10, 2011. In the letter Abbott states that "GPV conducted a retrospective review to determine whether there were any further death-only reports that may not have been reported to the FDA. The review period covered the reports received since the last periodic report date for each of our Abbott U.S. reportable products from 04-Dec-2009 through 22-Nov-2010."

125. At no time was Relator, an upper-level manager in the GPV division, informed or made aware of the "retrospective review" identified in Abbott's January 10, 2011, and based on her observations, the "retrospective review" never took place.

126. The 62 cases of death associated with the use of Humira identified in the 2010 FDA Form 483 is merely a small example of hundreds of death cases associated with Humira which were not properly reported to the FDA, as Abbott ordered all death cases associated with Humira to be designated "expected" and not reported to the FDA in an expedited manner from 2005 to 2010.

127. By concealing, and suppressing knowledge of, serious and unexpected events associated with Humira when taken for off-label use, Abbott dangerously promoted the unregulated use of the product for these purposes. Abbott's failure to properly report deaths associated with Humira for off-label uses poses a grave threat to patients who are left completely ignorant of the risks associated with the drug. The health care providers, whom patients rely on for information regarding the dangers posed by pharmaceutical products, depend almost exclusively on Abbott's FDA reporting to determine the safety of Humira. This is

precisely why Abbott is required to report serious cases, like death associated with Humira, to the FDA when it is unexpected.

128. Abbott's designation of "death" as an expected event for off-label uses of Humira was an unlawful attempt by Abbott to avoid FDA detection of the dangerous effects Humira has on patients, and in effect, promoted the continued prescription of Humira for these off-label uses, which were in turn reimbursed by government health care programs ignorant of the potentially fatal consequences of the Humira.

129. More egregiously, Abbot has applied for approval of Humira as a treatment for many of the currently off-label ailments for which it has received, and failed to properly report, serious and unexpected events such as death and on-set of cancer associated with Humira. Abbott is, on the one hand, attempting to benefit from patient off-label use of Humira by seeking approval, and thereby allowing Abbott to market Humira, for these uses, while on the other hand concealing from the FDA, government health care providers, health care physicians, and patients, the serious health risks associated with Humira for these uses.

130. Abbott's concealment of deaths and other serious adverse drug experiences associated with Humira is motivated exclusively by a desire to generate greater revenue, much of which generated from government health care providers, regardless of the mal-effects of the drug on patients.

3. Abbott created and maintains, to this day, a decentralized process for receiving and reporting adverse events designed to result in underreporting to the FDA

131. In order to dominate various drug and drugs markets, to increase the sales of Humira and to facilitate the continued reimbursement from Government Healthcare Programs for claims made by providers for Humira, Abbott misrepresented and/or concealed material

facts regarding adverse events attributable to Humira.

132. Abbott has been able to avoid detection in its underreporting of adverse events by creating a maze of divisions and databases in which adverse experiences reports received by Abbott are lost or miscoded, and are therefore not properly reported to the FDA and are undetectable during audits.

133. Abbott's organizational structure is vast, consisting of hundreds of subsidiaries and an equal number of divisions and departments. Abbott has, since at least 2005, intentionally and covertly maintained a post-marketing surveillance structure which allows for adverse drug experiences, when a patient experiences a reaction other than that intended by the treatment, to be reported to any one of these divisions and departments. FDA regulations require Abbott to create and maintain a post-marketing surveillance structure designed to record each of these events, determine whether the event constitutes an adverse drug experience and determine whether the event is serious and unexpected to be reported to the FDA within 15 days of receipt by Abbott. 21 CFR § 600.80(b)&(c). Abbott failed to create and maintain such a system.

134. Abbott receives reports of adverse drug experiences from a variety of sources, including patients using Humira, health care professionals who either prescribe Humira or become aware that a patient is taking Humira, sales representatives who receive feedback regarding patients' experiences with Humira, Partner corporations with which Abbott has agreements to market Humira, third party vendors who facilitate marketing and customer service for Humira, Abbott affiliates in non-U.S. markets selling Humira abroad, independent studies testing the safety and efficacy of Humira and legal filings.

135. Abbott's Global Pharmacovigilance ("GPV") Division is the only division formally tasked with receiving reports of adverse experiences from around the world and in turn

reporting the events to the FDA in a timely manner. GPV maintains the AEGIS database to record adverse experiences.

136. When the GPV is contacted by a patient with a potential adverse experience report, either by way of the package insert included with all Humira prescriptions providing the "1-800" contact number, from third-party vendors such as MyHumira or via transfer from another department, the event is documented in detail and given a "MedDRA" code. "MedDRA" refers to the international Medical Dictionary for Regulatory Activities. Each term in the dictionary is given an eight digit code. The terms included in the dictionary are exhaustive, including all terms pertaining to the safety and efficacy of a drug. The FDA requires that all adverse events be MedDRA coded to allow for a detailed assessment of the event and to ensure specificity in reporting. Only GPV employees are adequately trained in MedDRA coding adverse drug experiences.

137. However, given the wide array of sources for reports of adverse experiences, the following divisions and groups, together, also receive thousands of reports of adverse experiences:

- Global Pharmaceutical Operations ("GPO") - Division within Abbott charged with receiving and documenting "customer complaints identified by a consumer, health care professional of regulatory agency" according to Abbott. GPO maintains a database. In the past the database has been called PCA or, more recently, SOLTraqs. The database is not accessible to the public, medical professionals or the FDA. The database is designed to document product quality complaints, as opposed to adverse experiences associated with the drug

- Global Medical Information ("GMI")- Division within Abbott charged with "respond[ing] to medical inquiries," according to Abbott. GMI maintains the MIRSWeb database, which is designed to document medical inquiries received by Abbott.

- The Contact Center- Division within Abbott responsible for receiving calls from patients, healthcare providers and any other source of adverse event reports. The Contact Center is tasked with receiving all adverse events and medical inquiries

but does not handle Product Quality Complaints. The Contact Center has access to the AEGIS database, but merely enters basic information (i.e. name of the patient, date of the event, contact information) concerning potential adverse experience reports. Abbott's internal electronic system triggers a notice to GPV to update the database with complete information.

- Legal- Division within Abbott charged with handling all legal obligations of Defendant. No formal database exists in which the Legal Department enters adverse event complaints. The Legal department is expected to report all adverse events to GPV though no formal process exists to do so

- Affiliates – Non-U.S. divisions of Abbott charged with the operations of Abbott in various regions of the world. Many affiliates do not have access to AEGIS nor do they maintain a separate database for the collection and reporting of adverse experiences reported in other countries.

- Third Party Vendors- Companies contracted with by Abbott to conduct marketing programs such as research for pharmaceutical products, including conducting surveys and polls as well as compiling comments from patients. Third Party Vendors do not have access to AEGIS nor do they maintain a separate database for the collection and reporting of adverse events.

- Sales Representatives- Abbott employees charged with marketing and selling Abbott products, including Humira, to patients and health care providers. Sales representatives do not have access to AEGIS nor do they maintain a separate database for the collection and reporting of adverse events.

138. Such a fractured system is unique within the pharmaceutical industry, as Abbot does not maintain a single validated database in which all reports of adverse events and experiences are collected and ensure accurate reporting to the FDA.

139. In 2008, in response to an audit conducted by the European Medical Association, Abbott created an internal power point presentation detailing the flaws in its decentralized reporting mechanism. In the presentation Abbott recognized:

- 98% of events listed as medication errors, including adverse events, are due to Humira Pen;

- Abbott non-U.S. affiliates collect adverse event reports associated with Humira Pen but do not forward the event information to GPV to be reported to the FDA. 74 such events were identified in 2008;

- GPO does not proactively record medication errors or even recognize them and thus does not forward any information regarding these events to GPV;

- GPO and GMI both maintain non-validated databases wholly distinct from AEGIS. The Contact Center records all received post-marketing events on "pink slips" which are forwarded to GPV to be recorded into AEGIS.

140. Abbott recognized that the GPO database "MIRSWeb" and the "pink slips" used by the Contact Center were "not stable platforms or validated systems for capturing medications errors." Additionally, the multiple database system made it "very difficult to keep track of data and manage consistency." Finally, Abbott determined that attempts to "reconcile" the multiple databases could not be done in "real time" resulting in the "risk of missed adverse events contained in the database." Indeed, Abbott recognized in 2008 that the industry standard was to have one validated database to collect medication errors, including adverse events.

141. In June 2008, Abbott was keenly aware that reports of adverse experiences were being made to the wrong place and that no mechanism existed to account for these reports: "the assessment of unsuccessful injections [Humira] is complicated by a lack of a single process for collection of specified information and lack of coordinated database and documentation process that prevents collation, tracking and trending of the findings."

142. Abbott has not informed the FDA of its decentralized reporting structure, and has in fact concealed from the FDA reports of adverse experiences associated with Humira which were never forwarded to GPV. Abbott management, in fact, instructed its employees to not inform the FDA auditors of the decentralized reporting structure or multiple-database system.

143. Abbott recommended 16 alterations to its own post-marketing surveillance structure. To date Abbott maintains a decentralized structure in which several divisions receive reports of adverse drug experiences, the reports are either not recorded at all or are recorded in various, non-validated databases, and the individuals receiving the reports are either not trained

or not qualified to recognize adverse experiences.

4. Despite repeated warnings Abbott refused to alter its fraudulent reporting system

144. Abbott's recognition of the serious flaws in its post-marketing surveillance structure came in response to an audit performed by the European Medical Association ("EMA;" previously the "EMEA"). The 2007 audit found the following:

- Abbott's AEGIS database is not validated;
- Abbott utilizes automated searches to identify adverse drug experiences received and recorded in non-GPV databases, which do not adequately retrieve all relevant reports;
- AEGIS database is inadequate to ensure that all adverse events are being recorded and reported;
- Abbott has no process in place "to confirm that all adverse events . . . had been transferred to Global Pharamacovigilance for processing," including events associated with Humira. Three non-reported adverse events were identified in the audit report.
- Abbott improperly codes adverse experiences associated with the Humira Pen leading to underreporting of adverse events.

145. The results of this Audit were not made available to the FDA, U.S. government or state and municipal governments, to Relator's knowledge.

146. The results of the audit were confirmed by an internal "reconciliation" conducted by the GPV division in which all complaints received and documented by the GMI and GPO divisions from the date of product approval through October 31, 2007, regarding Humira, as well as Ritonavir, were assessed to determine whether all adverse drug experiences had been forwarded to GPV and subsequently reported to the FDA. Ms. Faith O'Neil, then Director of Medical Safety Surveillance, in an email sent on January 4, 2008, stated that 39 serious adverse drug experiences had never been reported to the FDA. Another 929 non-serious adverse drug

experiences had never been reported to the FDA.

147. In April 2010 Abbott was audited by the Medicines and Healthcare products Regulatory Agency ("MHRA"), the British government agency charged with ensuring the safety and efficacy of pharmaceutical and medical device products sold in England. The audit determined that out of 50 adverse event reports examined an average of 1.02 errors existed per report, meaning each report had at least one error.

148. The Results of the MHRA audit were not made available to the FDA, U.S. government or state and municipal governments.

149. From June through August of 2010 Relator was repeatedly contacted regarding adverse events which had received by Abbott, but had not been forwarded to Abbott and as a result the adverse experience had not been reported to the FDA. In particular, Relator was directly told:

- On June 1, 2010, that seven adverse events had been received by Abbott but had not been documented in the AEGIS database and thus not reported to the FDA and that 300 more cases may similarly have not been documented in AEGIS.
- On June 7, 2010, that four adverse events had been received by Abbott but had not been documented in the AEGIS database and thus not reported to the FDA.
- On June 23, 2010, that nine adverse events had been received by Abbott through third-party vendors but had not been documented in the AEGIS database and thus not reported to the FDA.
- On July 15, 2010, that nine adverse events, at least, had been received by Abbott but had not been documented in the AEGIS database and thus not reported to the FDA.
- On August 9, 2010, that 37 adverse events had been received by Abbott but had not been documented in the AEGIS database and thus not reported to the FDA.

150. Relator received similar notifications to those referenced in paragraph 116 regularly, identifying adverse experiences reported to Abbott but not properly reported to the

FDA. For example, as recently as January 17, 2011, Relator was notified that 17 adverse events had been received by Abbott but had not document in AEGIS and thus not forwarded to the FDA. Relator estimates that from 2005 to present, Abbott's intentionally decentralized post-marketing surveillance structure resulted in thousands of adverse drug experiences not being timely, or reported at all, to the FDA.

151. The FDA inspected Abbott's GPV division, including an inspection of adverse event reporting on November 15, 2010, through November 19, 2010, and December 13, 14, and 16, 2010. On December 16, 2010, the FDA issued a Form 483 Notice to Abbott, reporting the following observations:

- "Adverse drug experience information has not been reported to the FDA"
- "Not all adverse drug experiences that are both serious and unexpected have been reported to the FDA."
- A consumer adverse experience report of breast cancer associated with Humira which resulted in the death of the consumer was not reported to the FDA
- From January 1, 2010, through November 17, 2010, 62 adverse experience reports of death associated with Abbott pharmaceutical products were not reported to the FDA.

152. The FDA only inspected the GPV division of Abbott, as that is the only division Abbott has represented to the FDA as receiving and reporting adverse events. The 63 unreported deaths in less than a year identified by the FDA only accounted for those deaths reported to the GPV. The FDA did not inspect deaths, or other serious and unexpected adverse experiences, reported to GPO, GMI, the Call Center, Affiliates, Sales Representatives, Partners, Third Party Vendors or the Legal department, which were never reported to GPV and thus never reported to the FDA. In fact, Abbott management specifically instructed its audited employees to not disclose the alternate databases of the byzantine reporting system during the FDA audit.

153. On December 8, 2010, the Office of the CEO of Abbott released an end-of-the-year statement from Abbott CEO, Miles White, in which he recognized the challenges facing Abbott, specifically "competitive threats, including potential new competition for *Humira* – which we have to address. And these internal and external factors are currently affecting our stock price."

154. On January 10, 2011, Abbott responded to the FDA's Form 483 by letter, stating "we wish to reiterate GPRD's [Global Pharmaceutical R&D] commitment to meeting the requirements for post-marketing reporting of adverse drug experiences (21 CFR §314.80)."

5. Relator's Investigation

155. On December 17, 2010, Relator was assigned to investigate and assess a two fold increase in medical error reports regarding Humira by her direct supervisor, Vida Sajedi, and Ms. Sajedi's supervisor, Faith O'Neil. Relator was assigned to work with Dr. Holly Read, Senior Medical Director in the GMI division.

156. On December 21, 2010, Dr. Read sent an email to Relator, Ms. Sajedi and Ms. O' Neil, containing reports of medical error complaints made to Abbott. On December 28, 2010, Relator began to review the reports.

157. While investigating the exponential increase in medical error reports associated with Humira, Relator uncovered several issues regarding how events reported to Abbott were coded, potentially resulting in adverse drug experiences not being reported to the FDA. Relator began to perform an informal audit of the post-marketing surveillance structure.

158. Relator's informal audit revealed that the lack of a single validated database to collect adverse events maintained by a single division was directly resulting in adverse experiences being reported to the wrong division (non-GPV) and never forwarded to GPV,

faulty "reconciliation" of Abbott's various databases that failed to identify adverse experiences to report to the FDA, events being improperly coded and thus not properly identified as serious and unexpected adverse experiences requiring expedited reporting to the FDA, and lack of adequate training to identify adverse drug experiences.

159. On January 11, 2011, Relator presented her findings to her immediate supervisor, Ms. Sajedi, in a three-page summary of her findings. Relator started the meeting by saying that she was concerned with several issues related to Humira. As she began going through her observations Ms. Sajedi placed the summary on her desk and appeared to be disinterested in Relator's findings. Relator provided a detailed description of the various failures she had exposed. After Relator finished summarizing her findings, Ms. Sajedi said she would raise Relator's concerns to her supervisor, Ms. O'Neil.

a. Lack of Single Validated Database

160. Adverse drug experiences may be received by any Abbott division, department or associated group. Once Abbott receives a report of the adverse experience, regardless of which division, department or group received it, Abbott is obligated to report it to the FDA, either in 15 days if the event is serious and unexpected or in the PSUR if the event is non-serious. The lack of a single validated database to receive and document adverse events received from all departments has resulted in the thousands of adverse drug experiences not being reported to the FDA.

161. Over the course of Relator's tenure at Abbott she observed that GPO collected thousands of adverse events but because GPO was not given access to AEGIS, the only database designed to documents adverse experiences, it could not record these events to be reported to the FDA. For example if a patient called Abbott to report that he or she left Humira outside of the

refrigerator overnight then felt a burning sensation upon taking the drug, this would constitute both a product quality complaint, in regards to the efficacy of the drug after being kept at room temperature all night, and an adverse drug experience regarding the burning sensation. When complaints such as this one were made to GPO, they were coded only for the product quality complaint and not for the adverse event, resulting in the adverse drug experience not being reported to the FDA.

162. Relator confirmed that no system exists to collect adverse event information from the Legal division. Abbott relies exclusively on the Legal Division to self-report. Relator is aware of several occasions on which the Legal Division failed to notify GPV of adverse events it was aware of were not reported in another way, leading to the event being reported late or not at all. On January 6, 2011, Ms. O'Neil sent an email to Carleen requesting a meeting to discuss legal case processing. Ms. O' Neil explained that Abbott did not had a "closed loop system" with the Risk Management department, and thus had no mechanism for collecting reports of adverse experiences from this department.

163. Relator also determined that non-U.S. Affiliates are relied upon by Abbott to self-report adverse events they become aware of to GPV to be entered into AEGIS. Relator is aware of many occasions from 2005 to present during which Affiliates failed to identify adverse events either in a timely manner or at all, leading to the event being reported late or not at all.

164. On January 10, 2011, Relator was involved in a teleconference with Abbott affiliates in Brazil. During this conversation Relator was informed that the Brazil affiliates did not have an adequate understanding of what constituted an adverse drug experience. During a follow-up call with the Brazil affiliates on January 14, 2011, Relator took time to educate the affiliates on how to properly identify and document an adverse event. Based on Relator's

observations, prior to the January 14, 2011, conversation the Brazil affiliates were not properly receiving adverse experiences and as a result hundreds of adverse events occurring in Brazil were not forwarded to GPV and thus not reported to the FDA.

165. Additionally, affiliates in Canada repeatedly requested clarification regarding whether events reported to it qualified as adverse experiences that had to be forwarded to GPV.

166. Relator is further aware of adverse experiences reported to sales representatives and third party vendors, which were never forwarded to GPV and subsequently never reported to the FDA. In particular Relator is aware that Abbott maintained a practice of non-enforcing rules requiring Sales Representatives to write down adverse experiences to be submitted to GPV. Instead, these events were either relayed from the memory of representatives without sufficient detail to determine whether the event required expedited reporting or simply not forwarded.

167. The lack of a single validated database into which all departments and divisions could submit adverse experience reports resulted in hundreds of adverse experiences not being reported to the FDA that Relator was aware of and on belief, thousands more of which Relator was not aware.

b. Faulty "Reconciliation" Process

168. Relator's informal audit confirmed that despite Abbott's several databases being "reconciled" several adverse events were unidentified in only a one week period.

169. "Reconciliation" refers to Abbott's process of scanning its multiple databases for information recorded in one database that should be recorded in another. This process is not automated but requires individuals to manually assess every complaint received and stored in the MIRSWeb (GMI) or GPO databases for potential adverse experiences not initially identified

by those divisions and forward those complaints to GPV for input into the AEGIS database.

170. Abbott has hired two individuals on a contract basis to manually "reconcile" the MIRSWeb and GPO databases with AEGIS. Since 2007 at least six different individuals have held these positions. The contractors report an Abbott manager who is supposed to conduct a "spot check" to ensure that the contractors are adequately identifying adverse experiences.

171. Relator informed her supervisors in her 2010 findings that she had discovered a significant discrepancy between the number of adverse experiences received by GPO and the number of adverse experience reports forwarded from GPO to GPV to be reported to the FDA. GPO received far more adverse experience reports then it transferred to GPV, and thus GPV failed to report the non-transferred cases to the FDA.

172. Specifically, Relator identified the following flaws in the reconciliation process:

- The contract employees are not adequately trained to identify adverse experiences and do not have to pass any competencies prior to being approved to conduct the "reconciliation" process. On several occasions, prior to Relator conducting her informal audit, she was approached by the contract employees and asked whether specific events constituted adverse experiences which required being reported to the FDA

- The contract employees "reconciled" only new complaints, and did so on the day it was received by GPO. However, complaints would often be updated by GPO with more information in the days following the original creation of the complaint. Ms. Simon found that several of the complaints which had been updated, in just a five day span, included new information amounting to an adverse experience, which should have be recorded into AEGIS and reported to the FDA. However, because the contractors review only new complaints and not updated complaints, the reconciliation process never caught these adverse events and they were never reported to the FDA

- Abbott's "spot check" of the "reconciliation" results is inadequate to determine whether the "reconciliation was properly conducted. Specifically, the manager assigned to conduct the "spot check" failed to review a sufficient number of reports to validate the accuracy of the reconciliation. Further, neither the contract employees nor the manager assigned to oversee the reconciliation were required to issue reports or any other official statement that the reconciliation was accurate or reliable.

- Abbott did not create a second level review of non-GPV databases to ensure the validity of the "reconciliation process." As a result, if the contract employees failed to identify adverse experiences, these events were not reported to the FDA.

173. As evidence, Relator pointed out that the 2007 EMEA audit found at least three complaints received by the GMI division, and documented in the MIRSWeb database, involving adverse drug experiences that were never forwarded to GPV and thus never reported to the FDA, including a report of pregnancy exposure associated with Humira.

174. Relator has observed during her tenure at Abbott that contractors are not sufficiently trained to identify adverse drug experiences. On November 19, 2010, Relator was approached by Rick Katawake, Director of GMI, regarding several reports of expired products that had been made to GMI and documented in the MIRSWeb database but had not been forwarded to GPV and were not identified during "reconciliation." Mr. Katawake was unaware that patient use of expired Humira was an adverse drug experience that must be reported to the FDA. Relator informed Mr. Katawake that the event was an adverse drug experience that should have been reported to the FDA.

175. Relator's conversation with Mr. Katawake prompted her to investigate whether the contractors had been properly trained in identifying adverse drug experiences. One of the contractors at the time was Karen Tuenge. Ms. Simon approached Ms. Tuenge and asked her whether she had been identifying patient use of expired product as an adverse drug experience. Ms. Tuenge responded she had not, and stated that she had never been formally trained by Abbott as to what constituted an adverse drug experience.

176. After confirming that the "reconciliation" contractors had not been adequately trained to identify adverse drug experiences, Relator reviewed three to four days' worth of

complaints received by GPO and GMI and found several adverse drug experiences, which had not been identified during "reconciliation," including complaints of the use of Humira during pregnancy. None of the adverse experiences uncovered by Relator had been reported to the FDA.

177. On November 29, 2010, Relator reported to her supervisor, Ms. Sajedi, her findings that the contractors charged with the "reconciliation" process had never been formally trained to identify adverse drug experiences and as a result several adverse events received by Abbott had not been reported to the FDA. Relator recommended to Ms. Sajedi that Abbott review all reports received by the GPO and GMI divisions from the previous six to nine months, the entire time period of Ms. Tuenge's tenure as a "reconciliation" contractor, to determine whether all adverse drug experiences received by Abbott had been properly reported to the FDA.

178. Abbott never reviewed all reports received by the GPO and GMI divisions of Abbott in the six to nine months prior to November 19, 2010. Based on Relator's observations, hundreds of adverse drug experiences received by Abbott went unreported as a result of the faulty "reconciliation" process.

179. Relator's own informal audit, conducted in late December of 2010, uncovered at least five more unreported adverse experiences in the span of five days resulting from the faulty "reconciliation" process, a rate of at least one non-reported adverse drug experience per day. On belief, between 2008, when the "reconciliation" process was instituted, and present thousands of adverse experiences have gone unreported merely as a result of the discrepancies inherent in the "reconciliation" process.

180. Prior to 2008, without any "reconciliation" process to identify at least a portion

of adverse drug experiences not initially reported to GPV, thousands more adverse drug experiences went unreported to the FDA.

181. The "reconciliation" process does not attempt to identify adverse experience reports received by Abbott's corporate partners, third-party vendors, the legal division, sales representatives or non-U.S. affiliates. In fact, no formal or informal mechanism exists to identify or verify adverse experiences reported to these branches of Abbott and ensure they are reported to the FDA.

182. Based on Relator's observations thousands of adverse events received by Abbott through corporate partners, third-party vendors, the legal division, sales representatives and non-US affiliates were never identified due to the lack of any formal or informal mechanism at Abbott to do so, and as a result these adverse drug experiences were not reported to the FDA.

c. Improper Coding

183. Relator identified a second problem exacerbated by the deficiencies in Abbott's post-marketing surveillance structure: improper coding. Relator discovered that regardless of where the adverse experience is reported, either to GPV or non-GPV divisions, adverse events are improperly coded.

184. Adverse experiences are coded based on a description of the specific event. The individual from Abbott receiving the adverse experience report must document the event in detail. A MedDRA[2] code is assigned for each specific instance of the event, which often results in more than one MedDRA code per event. Each individual MedDRA code indicates whether

[2] MedDRA is an acronym for Medical Dictionary for Regulator Activities and is a standardized global coding system that allows all aspects of medical and pharmaceutical information to be electronically categorized. The types of data coded include Safety and Efficacy, Laboratory Data, Medical History, Family and Social History, and Physical Examination Data. There is a unique 8 digit code for each entry in the MedDRA dictionary. For example, Urticaria is a MedDRA Term with MedDRA Code 10046735.

the event is a serious adverse experience requiring expedited reporting to the FDA, a non-serious adverse experience requiring non-expedited timely reporting to the FDA, or a non-adverse experience not requiring reporting to the FDA.

185. Improper coding occurs when the improper MedDRA codes are inputted to describe the event reported. For example, appendiceal perforations are a potential side effect of Humira. Whether the initial contact is coded as an appendiceal perforation (accurately) or as an appendectomy (surgical response to the appendiceal perforation) dictates how the event is reported (i.e. serious and unexpected adverse drug experience, adverse drug experience, no adverse drug experience).

186. Relator identified several ways in which adverse experiences were being improperly coded:

- Case analysts employed in the GPV division of Abbott failed to document details of adverse experience reports, making it impossible to properly code the event and subsequently report the event to the FDA when required.

- Case analysts in non-GPV divisions were not proficient in assigning MedDRA codes to narrative adverse experience reports, resulting in improperly coded complaints which could not be properly identified as an adverse experience during reconciliation and subsequently filed with the FDA.

187. Relator's informal audit exposed at least seven cases, over the span of just five days, in which the adverse drug experience associated with Humira as documented in the narrative was issued an incorrect MedDRA code, to effectively make it appear that the event was caused by user error. Specifically:

- Case 10P-163-0620061-00 - A narrative reflecting that the patient suffered a punctured finger while using Humira was improperly coded as "Wrong Injection Technique"

- Case 10P-163-0623647-00 - A narrative reflecting that the patient suffered from an injected index finger while using Humira was improperly coded as "Wrong Injection Technique"

- Case 10P-163-0588726-00 - A MedDRA code reflecting that the Humira Pen fell apart while a patient was using it was not included in the narrative

- Case 10P-163-0626020-00 & Case 10P-163-0626721-00 - Two narratives reflecting that patients suffered from the adalimumab medication being squirted into their eyes was improperly coded as "Wrong Injection Technique"

- Case 10P-163-0628265-00 - A narrative reflecting that the patient suffered from a punctured thumb while using Humira was improperly coded as "Wrong Injection Technique."

188. Relator has since identified hundreds more adverse events received by Abbott that were improperly coded not to reflect adverse drug experiences and thus not reported to the FDA. For example, cases 0640989 , 0641963, 0642394, 0645568, 0638736, 0642770, 0641006, were each coded to reflect the patient used the "wrong injection technique" despite each patient suffering from unnecessary pain and injury, events which were not coded and thus not reported to the FDA.

189. Abbott also routinely and systematically miscoded underdosing of patients associated with Humira. When Abbott received a report that a patient taking Humira had not received the entire dose, regardless of the reason (e.g. the Pen was not completely filled, the pen failed to inject the full amount of the drug, a portion of the drug failed to stay injected within patient's body, etc.) employees were ordered to code the event as a "patient technique error," not an adverse drug experience and thus not reported to the FDA.

190. On August 24, 2009, Pat received an email from Mary Mathieu, Senior Product Quality Manager for GPO, explaining that when GPO received a complaint "we do not track or code missed dose." According to Relator, a missed dose, regardless of the cause, is an adverse event that should be recorded in AEGIS and reported to the FDA. By not coding the adverse event, it cannot be identified in "reconciliation" and is thus never reported to FDA.

191. Abbott, by miscoding under dosing as a non-adverse drug experience, suppressed knowledge from the FDA and government health care providers that patients were receiving a smaller dose of Humira than was being reimbursed by the government health care providers. From at least 2005 through present Abbott has miscoded and illegally failed to disclose thousands of reports of under dosing.

192. Abbott's failure to report under dosing associated with Humira has resulted in government health care providers overpaying for tens of thousands of Humira prescriptions, resulting in a loss of hundreds of millions of government dollars.

193. The consequences of improper coding are twofold: (1) if an adverse experience is improperly coded in non-GPV division it cannot be identified either in the "reconciliation" process or otherwise to be forwarded to GPV and subsequently forwarded to the FDA; or (2) if an adverse experience is improperly coded as a non-serious adverse experience, as opposed to a serious and unexpected adverse experience, the event is not reported to the FDA at the proper time and consequently, the FDA fails to notice a trend in the effects of the drug.

194. For example, if four serious adverse events, all identical, are reported on the same day, but only one is properly coded as a serious adverse event while the other three are coded as non-adverse events, only one will be reported in the 15 Alert report. Defendant reports the coded serious adverse event within fifteen days of its occurrence and reports the remaining three events in its quarterly or yearly PSUR. As a result, the FDA and health care providers fail to identify a potential trend in risks presented by the drug.

195. The consequences of such failures are tremendous. Physicians prescribe Humira without any knowledge of unreported adverse effects subjecting their patients to a potentially hazardous product. Additionally, the FDA fails to notice a potential trend in the effects of that

batch of drug and instead notices only that four similar events occurred over the course of three months or a year, far from a trend, rendering it useless to prevent further distribution of the product or warn the public about the new risks associated with Humira. As a result, the FDA continues to approve Abbott's supplemental requests to market Humira as a treatment for a greater number of illnesses and government health care payers reimburse Defendant for dangerous products which would not have been reimbursed had Defendant properly reported the events.

d. Lack of Adequate Training

196. Finally, Relator's investigation revealed that Abbott has received a substantially higher number of US adverse event reports than adverse event reports from outside the US. This was concerning to Relator as all adverse events, whether they occur within the US or internationally, must be reported to the FDA. 21 C.F.R. § 314.80. Relator determined that affiliates in non-US markets were not adequately trained to identify adverse experiences that adverse experiences reported to affiliates were not being forwarded to GPV, and consequently these events were being under reported to the FDA. She noticed that while a detailed factual narrative was being recorded in the Form or Complaint, the narrative was not being forwarded to GPV.

197. As Relator has witnessed, adverse event reports may be received by any of the various divisions. For example, a customer believing she has a quality complaint may contact the GPO division, when in fact the substance of the complaint is an adverse event. Due to lack of training of GPO employees to recognize and report adverse events, the adverse event is not forwarded to GPV.

198. In addition to the breakdowns in the reconciliation process, Ms. Simon noticed

that both GPO and the Contact Center lacked proper training to identify and code adverse events. When assessing both the Product Quality Complaints and the Case Processing Form she noticed several narratives that should have qualified as adverse events but were not coded as such. On several occasions narratives that clearly warranted adverse event coding were coded as non-adverse events. As a result the events were not properly recorded in AEGIS followed up or otherwise investigated or reported to the FDA.

199. A 2011 Audit of the GPV found that:

- Training of employees in identifying adverse events was inadequate
- The training materials supplied by Abbott to teach employees how to identify adverse events lacked discussion of required special situations, including medication error, breast feeding and off label use of the product
- Abbott employees were not required to be trained on identifying adverse events
- Abbott did not set dates by which employees were to be trained in identifying adverse events
- At least some distributors of Abbott drugs are not trained in identifying adverse events and reporting to Abbott.

6. Abbott repeatedly misrepresented that it was in compliance with FDA adverse experience reporting requirements.

200. As part of its New Drug and Drug License Application for Humira, Abbott via its execution of various forms and certifications, including but not limited to FDA Form 356h, expressly and impliedly certified that it would comply with all adverse experience reporting requirements, including the reporting requirements delineated in 21 C.F.R. §600.80. Accordingly, compliance with 21 C.F.R. § 600.80 and the adverse event reporting obligations was a condition precedent to obtaining and maintaining the FDA's approval to promote and sell Humira to consumers, including consumers on governmental assistance.

201. Abbott was required to certify and promise that it would report all serious

adverse events and adverse events associated with Humira in it Drug License Application, in every PSUR submitted quarterly from January 1, 2003 through December 31, 2006, and annually thereafter, and in every application or supplementary application to the FDA requesting permission to market and distribute the product as treatment for conditions not currently allowed.

202. For the sale of Humira alone, Abbott has certified to the FDA at least 20 times since 2002, that it is upholding its legal obligation to report all serious adverse events and adverse events in relation to Humira.

203. Abbott Certified in BLA 125057 on or about March 28, 2002 and subsequent supplements to BLA 125057 on December 18, 2002 and December 30, 2002 (on the equivalent of FDA form 365H and pursuant to 21 C.F.R. Parts 314 and 601):

> to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions…to submit safety update reports as provided for by regulation or as requested by FDA…to comply with all applicable laws and regulations that apply to approved applications including…6. Regulations on Reports in 21 C.F.R. 314.80, 314.81, 600.80, and 600.81…The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

204. Abbott made similar certifications regarding adherence to FDA reporting requirements when submitting to the FDA for Humira supplemental BLAs: 125057/16, 125057/23, 125057/45; 125057/46; 125057/60, 125057/62; 125057/71, 125057/89, 125057/94, 125057/95, 125057/108, 125057/110, 125057/114, 125057/196, 125057/213, 125057/215, 125057/128, 125057/161, 125057/224, 125057/254, 125057/254, 125057/255, 125057/271, 125057/276, and at least 6 additional supplemental BLA for additional indications.

205. Additionally, in response to every audit and inspection of its post-marketing

surveillance structure, Abbott categorically denied any wrong doing and certified that it's reporting mechanism was adequate to identify adverse experiences in compliance with FDA regulations.

7. Relator's Concerns Were Verified by a 2011 Internal Audit of Abbott's Post Marketing Surveillance Structure.

206. In 2011, Abbott conducted an internal audit, performed by Pietrek Associates GMBH. The audit inspected the GPV division of Abbott. On September 19, 2011, nine months after Relator first raised her concerns to her superiors, an internal audit issued findings corroborating Relator's observations.

207. The internal audit the auditors found, among other things:

- "Deficiencies in Pharmacovigilance training of GPV and non-GPV staff members." The audit specifically pointed out, among other things, that "[t]he training material for All Employee AE Training lacked discussion of required special situations, including medication errors, breast feeding and off label use." "not all distributors are trained on AE [adverse experience] collection and reporting to Abbott." The auditor rated the deficiency a major concern.

- "Deficiencies in Reconciliation of AE [adverse experience] Data Sources." Specifically, the audit observed that (i) "Not all medication errors and AEs are identified from product complaints or medical information or clinical trial data and captured in AEGIS," (ii) "Currently there is no routine reconciliation performed with market research vendors," (iii) "Product complaint reconciliation examples were not reviewed in a timely manner to avoid late reporting if a serious ADR would be identified upon GPV review." The auditor noted deficiencies in attempts to identify adverse experiences received by GMI, GPO, vendors and the Contact Center. The auditor identified roughly a dozen adverse experiences reported to various non-GPV divisions of Abbott in the course of only five days, which were not properly identified and subsequently not reported to the FDA. The auditor rated the deficiency a major concern.

208. The results of this 2011 internal audit were not made available to the FDA or other state or municipal governments.

209. The audit only inspected non-GPV divisions to the extent that it assessed the accuracy of the "reconciliation" process, which the auditor declared a "major" concern. The

audit did not review non-GPV databases or address the lack of a single validated database, as the inspection was only of GPV. To the extent that adverse experiences were not forwarded to GPV due to inadequacies and deficiencies in training and recording such events, such events would have been concealed from the auditor.

210. Abbott has not taken corrective action since the internal audit findings were released to ensure more thorough training or to establish greater accuracy in the "reconciliation" process.

B. ABBOTT ILLEGALY SUPPRESSED KNOWLEDGE OF ITS UNLAWFUL CONCEALMENT SCHEME

1. Abbott ordered employees not to reveal its unlawful concealment scheme to the FDA

211. In a 2009 annual lunch meeting with all post-marketing safety managers, including Relator, Ms. Heimberger was asked by Relator how the post-marketing safety managers had been performing. Tracey replied that "we are learning." She continued to say that "you are either in the boat or out of the boat. Once you are out of the boat you don't get back in." Relator understood Ms. Heimberger's statement to mean that every employee should obey orders without question, and failure to adhere to this order would result in adverse professional consequences.

212. In November 2010 Abbott's GPV division was inspected by the FDA. Abbott organized a staging room for the FDA in which the FDA conducted its inspection of GPV records. Relator worked with the other individuals in GPV to assist the FDA in the inspection. Other individuals who participated in the FDA audit included Ms. O' Neil, Ms. Sajedi, Frank Pavelske, Senior Manager of Quality Systems, Maria LaFleur, of the GPO division and Marty Murawski Director of Product QA.

213. On November 18, 2010, Relator was in the staging room with Ms. O'Neil, Mr. Murawski and Ms. LaFleur. While the individuals were waiting for the FDA inspector, Ms. O'Neil ordered the group not to discuss the multiple database system stating, "Listen, if you are asked, do not let it be known that we have two databases- quality and safety. We don't want to get into that with them." Both Marty and Maria smiled and laughed. Marty stated "absolutely," then turned to Marian and explained "talk to them about anything else but that." Maria, relaying her conversations with the FDA inspector stated "I was just down that and I was talking to them about quality stuff and making small talk." Marty stated "good."

214. The FDA audit found that Abbott had failed to report 62 serious adverse events which were associated with death and at least one case associated with cancer. In response to the finding, Abbott failed to divulge the cause of the reporting failure and failed to take corrective action by creating and implementing a single validated database to collect adverse event reports and ensure their reporting to the FDA.

2. Abbott demoted Relator in retaliation for identifying and presenting the illegal concealment scheme to her supervisors

215. On January 18, 2011, Ms. Simon was ordered to a meeting with Ms. Sajedi and Ms. O'Neil in which she was reprimanded for her findings regarding inadequate adverse event reporting. Relator walked into the meeting and was told by Ms. Sajedi, that Ms. Sajedi had found Relator's report, on her desk and did not remember receiving it. She stated that after finding the report on her desk she had read it. Ms. Sajedi stated "if this got in the wrong hands, it could have far reaching consequences for the company; this could have major far reaching impact for Abbott." Relator agreed and stated that the seriousness of the issues precipitated her initial meeting with Ms. Sajedi on January 11, 2011. Ms. Sajedi denied ever seeing the summary.

216. Ms. O'Neil, Ms. Sajedi's supervisor, was sitting next to Relator during the meeting and stated that the summary was "subjective." Ms. O'Neil raised her voice and stated that Relator's summary was not in GPV's 2011 goals. Ms. O'Neil demanded to know who authorized Relator to look into the adverse experience reporting. Relator responded that she had been ordered to look into the increase in medication errors. Ms. O'Neil told Relator that there was no reason for her to look into every process. She then told Relator "you did not act as a representative of upper management" in conducting her own investigation. Ms. O'Neil reprimanded Relator for going outside the GPOV division to conduct her informal audit and for not following proper command.

217. The meeting ended with both Ms. Sajedi and Ms. O' Neil getting up and walking out to attend another meeting.

218. In March 2011 Ms. Simon received a "Partially Achieved" rating for her 2010 evaluation, her lowest evaluation during her tenure at Abbott. The evaluation stated that the basis for the "PA" was that Pat had taken two weeks off to serve Jury Duty and that she had performed the "gap analysis" without management approval. The "gap analysis" referred to the investigation of under-reporting of Adverse Events for Humira.

219. Relator filed complaints with both Employee Relations and the Vice President of Global Medical Services, Tracey Heimberger, challenging the validity of the evaluation. Specifically, in a March 28, 2011, email to Ms. Heimberger, Relator explained that she believed Ms. Sajedi and Ms. O'Neil were retaliating against her for uncovering issues concerning the decentralized post-marketing surveillance system instituted and maintained by Abbott. Relator stated I am 'in the boat' and very committed to our strategic objective or Protecting Patient's Worldwide." *Id.*

220. In April, 2011, Relator contacted Essex Mitchell with the Office of Ethics and Compliance at Abbott. Relator explained that she believed she was being treated unfairly. Abbott sent an internal auditor, Jojo Munji, to meet with Relator. During this meeting Mr. Munji expressed to Relator that Abbott has a history of treating employees who raise issues regarding Abbott practices similar to the way Relator had been treated.

221. A second meeting was scheduled to allow Relator the opportunity to present her case. In attendance at the meeting were Relator, Mr. Munji and Laura Hennesy, a senior manager in Employee Relations at Abbott. At this meeting Relator presented, for the third time, her findings regarding the non-reporting of adverse events. Relator prepared four large binders and 3 CD-ROMs consisting of audits, internal reports, communications, adverse event reports and her own findings to corroborate her findings. On January 23, 2012, the Office of Compliance closed its investigation finding that Abbott had not violated any policies and that Relator's concerns were unfounded.

222. Relator's 2011 mid-year performance evaluation, issued on September 30, 2011, was 16 legal size pages in length and consisted of over two dozen areas in which Relator could improve. As a result of the evaluation Relator was called into a meeting in January, 2012, and given two options: (1) she could remain at her current position, but be expected to exceed all expectations and goals, or (2) accept a demotion from Grade 20 to Grade 18, resulting in limited responsibilities but maintaining the same pay scale.

223. Relator accepted the demotion. After her demotion Relator has not had access to any information that would allow her to assess whether Abbott has continued to perpetrate the fraud she exposed.

224. Relator left Abbott in May, 2012.

VI. CONCLUSION

225. The concealment schemes alleged in the Complaint were created, maintained and orchestrated by upper level management at Abbott, some of whom have benefitted and continue to benefit from the unprecedented success of Humira. In order to effectuate their wrongdoing which drained billions of health care dollars from public third party payers, Defendants knowingly withheld significant medical information concerning the safety and efficacy of Humira only known to it and as a result placed at risk and caused injury to patients of all ages, suffering from chronic incurable ailments. Therefore, while this Complaint sets forth overt acts, names and dates, what should not be forgotten is the impact of Defendants' conduct on an ever-growing population of American patients, the elderly and the most juvenile, who have been given a dangerous drug as a result of Abbott's suppression of vitally important information crafted to maximize the economic utility of a drug company and its leadership.

VII. COUNTS

COUNT ONE
Federal False Claims Act U.S.C. § 3729(a)(1)(A)3
Against All Defendants

226. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

227. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729(a)(1)(A).

228. By virtue of fraudulent concealment, misrepresentations and submission of non-reimbursable claims described above, Defendants knowingly presented, or caused to be

[3] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(1).

presented false or fraudulent claims capable of influencing the government's decision to pay, for improper payment or approval of prescriptions for Humira.

229. The United States, unaware of the falsity of fraudulent nature of Defendants' claims, paid the claims.

230. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT TWO
Federal False Claims Act 31 U.S.C. §§ 3729(a)(1)(B)[4]
Against All Defendants

231. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

232. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

233. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim.

234. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

235. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT THREE
Conspiracy To Submit False Claims 31 U.S.C. §3729(a)(1)(C)[5]

[4] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(2).

Against All Defendants

236. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

237. This is a claim for treble damages and civil penalties under the Flase Claims Act, 31 U.S.C. § 3729(a)(1)(C).

238. By virtue of fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and/or (a)(1)(B).

239. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

240. By reason of these payments the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR
California False Claims Act., Cal. Gov't Code § 12651*et seq.*
Against All Defendants

241. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

242. This *is* a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code§ 12651 *et seq.*

243. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to

[5] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(2).

be presented to the California Medicaid Program *(i.e.,* Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

244. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the California False Claims Act.

245. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

246. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIVE
Connecticut False Claims Act,
Conn. Gen. Stat. §§ 17b-301a -17b-301p (2010 Supplement)
Against All Defendants

247. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

248. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-30la-17b-30lp (2010 Supplement).

249. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above; Defendants knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement

250. Moreover by virtue of the fraudulent concealment, misrepresentations and

submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Connecticut False Claims Act.

251. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

252. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIX
Delaware False Claims Act,Del. Code Ann. tit. 6, § 1201*et seq.*
Against All Defendants

253. Relator re-alleges arid incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

254. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit 6, § 1201 *et seq.*

255. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

256. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violation of the Delaware False Claims Act.

257. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been

allowed and may not have otherwise been submitted.

258. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVEN
Florida False Claims Act, Fla. Stat.Ann. § 68.081*et seq.*
Against All Defendants

259. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

260. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*

261. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

262. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Florida False Claims Act.

263. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

264. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHT
Georgia False Medicaid Claims Act, GA. Code Ann.§ 49-4-168 *et seq.*

Against All Defendants

265. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

266. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, GA. Code Ann. § 49-4-168 *et seq.*

267. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

268. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Georgia False Medicaid Claims Act.

269. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

270. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINE
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*
Against All Defendants

271. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

272. This is a claim for treble damages and civil penalties under the Hawaii False

Claims Act, Haw. Rev: Stat. § 661-22 *et seq.*

273. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using or causing to be made or used a false record or statement.

274. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Hawaii False Claims Act.

275. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

276. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TEN
Illinois Whistleblower Reward and Protection Act,
740 Ill.Comp. Stat.175/1*et seq.*

277. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

278. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. *Comp.* Stat.175/1 *et seq.*

279. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent

claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

280. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Illinois Whistleblower Reward and Protection Act.

281. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

282. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT ELEVEN
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5
Against All Defendants

283. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

284. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code '§ 5-11-5.5.

285. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made o:t used a false record or statements

286. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit

violations of the Indiana False Claims and Whistleblower Protection Act.

287. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWELVE
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann.§ 46:439.1*et seq.*
Against All Defendants

288. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

289. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann.§ 46:439.1 *et seq.*

290. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

291. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Louisiana Medical Assistance Programs Integrity Law.

292. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

293. By reason of these payments, the Louisiana Medicaid Program has been

damaged, and continues to be damaged in a substantial amount.

COUNT THIRTEEN
Massachusetts False Claims Act, Mass. Ann. Laws cb.12, § S(A)-(0)
Against All Defendants

294. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

295. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O).

296. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

297. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Massachusetts False Claims Act.

298. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

299. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOURTEEN
Michigan Medicaid False Claims Act, MCLA § 400.601 *et seq.*
Against All Defendants

300. Relator re-alleges and incorporates by reference the allegations contained in

the preceding paragraphs of this Complaint.

301. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA § 400.601 *et seq.*

302. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

303. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Michigan Medicaid False Claims Act.

304. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

305. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

306. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

COUNT FIFTEEN
Montana False Claims Act; Mont. Code Anno. §17-8-401*et seq.*
Against All Defendants

307. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Anno. § 17-8-401 *et seq.*

308. By virtue of the fraudulent concealment, misrepresentations and submissions

of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or 1mowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

309. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Montana False Claims Act.

310. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

311. By reasons of these payments, the Montana Medicaid Program has been damaged and continues to be damaged in a substantial amount.

COUNT SIXTEEN
Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*
Against All Defendants

312. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

313. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §357:010 *et seq.*

314. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Nevada Medicaid Program false or :fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

315. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Nevada False Claims Act.

316. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

317. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVENTEEN
New Hampshire Medicaid Fraud and False Claims Act,
N.H. Rev. Stat. Ann. §167:61-b, *et seq.*
Against All Defendants

318. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

319. This is a claim for treble damages and civil penalties under the New Hampshire. Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann.§ 167:61-b, *et seq.*

320. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the. New Hampshire Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

321. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Hampshire Medicaid Fraud and False Claims Act.

322. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent

nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

323. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHTEEN
New Jersey False Claims Act; N.J. Stat.§ 2A:32C-1 *et seq.*
Against All Defendants

324. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

325. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat.§ 2A:32C-1 *et seq*.

326. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable chums described above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statements

327. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Jersey False Claims Act.

328. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

329. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged ina substantial amount.

COUNT NINETEEN
New Mexico Medicaid False Claims Act,
N.M. Stat. Ann., 1978, § 27-14-1*et seq.*
Against All Defendants

330. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

331. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable chums described above, Defendants knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

332. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Mexico Medicaid False Claims Act.

333. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

334. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged ina substantial amount.

COUNT TWENTY
New York False Claims Act, N.Y. State Fin.Law§187 *et seq.*
Against All Defendants

335. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

336. This is a claim for treble damages and civil penalties under the New York

False Claims Act, N.Y. State Fin. Law§ 187 *et seq.*

337. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

338. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New York False Claims Act.

339. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

340. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY ONE
North Carolina False Claims Act, 52 N.C.G.S.§1-605 *et seq.*
Against All Defendants

341. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

342. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, 52 N.C.G.S. § 1-605 *et seq.*

343. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment

or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

344. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the North Carolina False Claims Act.

345. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have otherwise been submitted.

346. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY TWO
Oklahoma Medicaid False Claims Act; 63 Okl.St.§ *5053-et seq.*
Against All Defendants

347. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

348. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*

349. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be make or used a false record or statement.

350. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit

violations of the Oklahoma Medicaid False Claims Act.

351. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claim that otherwise would not have been allowed and may not have been otherwise submitted.

352. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY THREE
Rhode Island False Claims Act; R.I. Gen. Laws§ 9-1.1-1*et seq.*
Against All Defendants

353. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

354. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws§ 9-1.1-1 *et seq.*

355. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement.

356. Moreover by virtue of the fraudulent concealment, misrepresentations and subm1ssions of non-reimbursable claims described above, Defendants conspired to commit violations of the Rhode Island False Claims Act.

357. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

358. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY FOUR
Tennessee Medicaid False Claims Act,
Tenn. Code Ann.§ 71-5-181*et seq.*
Against All Defendants

359. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

360. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

361. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

362. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Tennessee Medicaid False Claims Act and the Tennessee False Claims Act.

363. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

364. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY FIVE
Texas Medicaid Fraud Prevention Act,
Tex. Hum. Res. Code Ann.§ 36.001 *et seq.*

Against All Defendants

365. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

366. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

367. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

368. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Texas Medicaid Fraud Prevention Act.

369. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

370. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY SIX
Virginia Fraud Against Taxpayers Act,
Va. Code Ann. §8.01-216.1*et seq.*
Against All Defendants

371. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

372. This is a claim for treble damages and civil penalties under the Virginia Fraud

Against Taxpayers Act,.Va. Code Ann. §8.01-216.1 *et seq*_

373. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

374. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Virginia Fraud Against Taxpayers Act.

375. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

376. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY SEVEN
Wisconsin False Claims Act; Wis. Stat.§ 20.931 *et seq.*
Against All Defendants

377. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

378. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat.§ 20.931 *et seq*.

379. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or

approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

380. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Wisconsin False Claims Act.

381. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

382. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY EIGHT
District of Columbia False Claims Act,
D.C. Code § 2-308.14 *et seq.*
Against All Defendants

383. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

384. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §2-308.14 *et* seq.

385. By virtue of the fraudulent concealment, misrepresentations and submissions of non- reimbursable claims described above, Defendants knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement.

386. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described-above, Defendants conspired to commit

violations of the District of Columbia False Claims Act.

387. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

388. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY NINE
City of Chicago False Claims Act,
Chicago Mun. Code Chapter 1-22-010, *et seq.*
Against All Defendants

389. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

390. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act, Chicago Municipal Code Chapter 1-22-010, *et seq.*

391. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the City of Chicago false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement

392. Moreover by virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the City of Chicago False Claims Act.

393. The City of Chicago, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed and may not have been otherwise submitted.

394. By reason of these payments, the City of Chicago bas been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY
Arkansas Medicaid Fraud False Claims Act
Ark. Code Ann. § 20-77-901

394. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

395. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.

396. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and or conspired to present false or fraudulent claims for payment or approval.

397. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

398. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-ONE
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-303.5 et seq.

399. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

400. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*

401. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Colorado Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and or conspired to present false or fraudulent claims for payment or approval.

402. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

403. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-TWO
Iowa Medicaid False Claims Act
Iowa Code § 685.1 et seq.

404. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

405. This is a claim for treble damages and civil penalties under the Iowa Medicaid False Claims Act, Iowa Code § 685.1 *et seq.*

406. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a

false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

407. The Iowa Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

408. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-THREE
Maine False Claims Act
Me. Rev. Stats. Ann. tit. 5 § 215 et seq.

409. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

410. This is a claim for treble damages and civil penalties under the Maine False Claims Act, Me. Rev. Stats. Ann. tit. 5§ 215 *et seq.*

411. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Maine Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

412. The Maine Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

413. By reason of these payments, the Maine Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-FOUR
Maine False Claims Act

Me. Rev. Stats. Ann. tit. 5 § 215 et seq.

414. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

415. This is a claim for treble damages and civil penalties under the Maryland False Claims Act Md. Code Ann. Health-Gen § 2-601 *et seq.*

416. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

417. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

418. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-FIVE
Minnesota False Claims Act
Minn. Stat. § 15c.01 et seq.

419. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

420. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act Minn. Stat. § 15c.01 *et seq.*

421. By virtue of the fraudulent concealment, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

422. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

423. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-SIX
Federal False Claims Act, 31 U.S.C. 3729(a)(1)(G),
Against All Defendants

424. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

425. By their actions and inactions described above, Defendants have received funds from the Plaintiffs for knowingly false claims and has failed to timely return such funds despite a legal obligation to do so once Defendants have knowledge of the fraudulent receipts, pursuant to the Federal False Claims Act, as amended, 31 U.S.C. 37299 (a)(1)(G).

426. Despite Relator's reports to Defendants that Defendant's business model was resulting in improperly withholding or untimely submitting adverse event reports, Defendants intentionally continued its said illegal practices withhold or delay adverse event reporting.

427. After Defendants learned from Relator that their actions and inactions violated their adverse reporting requirements, Defendants failed to return to the Plaintiffs the funds it had

fraudulently received from the Plaintiffs. Further, Defendants knowingly made false reports to the FDA for the purpose of continuing to retain the fraudulently received payments.

428. Plaintiffs have been damaged by Defendants' failure to return such funds in an amount to be determined at trial

VIII. PRAYER

WHEREFORE, Relator requests that judgment be entered against Defendants, ordering that:

a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the State False Claims Acts;

b. Defendants pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729, plus three times the amount of damages the United States has sustained because of Defendants' actions, plus the appropriate amount to the States and municipalities under similar provisions of their false claims acts;

c. The Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state and municipal false claims acts;

d. The Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. §3730(d) and similar provisions of the State False Claims Acts;

e. Defendants be enjoined from concealing, removing, encumbering or otherwise disposing of assets which may be required to pay civil monetary penalties imposed by the Court;

f. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

g. The United States, the States, Municipalities and Relator recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Relator hereby demands a trial by Jury.

Respectfully submitted,

By: _____
Nola J. Hitchcock Cross
One of Relator's Attorneys

Robin Potter, Esq.
Shankar Ramamurthy, Esq.
ROBIN POTTER & ASSOCIATES, P.C.
111 East Wacker Street
Suite 2600
Chicago, Illinois 60601
(312) 861-1800
robin@potterlaw.org
shankar@potterlaw.org

Nola J. Hitchcock Cross, Esq.
Noah Reinsein, Esq.
CROSS LAW FIRM, S.C.
Lawyers' Building
845 N. 11th Street
Milwaukee, Wisconsin 53233
(414) 224-0000
njhcross@crosslawfirm.com
nreinstein@crosslawfirm.com